

**UNITED STATES DEPARTMENT OF COMMERCE****United States Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

09/014,087 01/27/98 CARLYLE

W 07001/065001

EXAMINER

QM32/0524

PETER S DARDI, PH.D.
WESTMAN, CHAMPLIN & KELLY, P.A.
SUITE 1600-INTERNATIONAL CENTRE
900 SECOND AVENUE SOUTH
MINNEAPOLIS MN 55402-3319

PREBILIC, P

ART UNIT

PAPER NUMBER

3738

DATE MAILED:

05/24/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

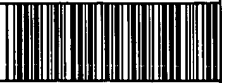
Office Action Summary

Application No.
08/014,087

Applicant(s)
Carlyle et al

Examiner
Paul Prebilio

Art Unit
3738



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Mar 2, 2001
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 14, 15, and 21-29 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 14, 15, and 21-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

Art Unit: 3738

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 2, 2001 has been entered. In addition, the amendment filed January 29, 2001 has been entered as per Applicant's instructions.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-11 and 29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Referring to claims 1 and 29, the newly added language of claims 1 and 29 pertaining to the crosslinking functional groups lacks original support and was not originally contemplated by the Applicant.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 3738

Claims 1-11 and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With regard to claims 1-11 and 29, referring to the Section 112, first paragraph rejection above, if it can be shown that the new subject matter has original inherent and implicit support, then it is the Examiner's objection that this subject matter does not have explicit support. In other words, the claimed subject matter at least lacks antecedent basis from the specification as required.

With regard to claim 29, it is not clear what is meant by the terminology "intrinsically active."

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Art Unit: 3738

Claims 1-6, 9-11, 14, and 21-29 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 4, 8-11, 13, and 15 of copending Application No. 09/186,810. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter of the copending claims is so similar to the presently claimed subject that it reads on it and is at least clearly obvious thereover.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 25 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Cahalan (US 5,308,641) wherein human or animal tissue is used as the solid surface and the biomolecule is one of the growth factors listed on column 6, lines 14-18; see the whole document, especially the abstract, column 4, lines 20-43, and column 6, lines 8-28. It is noted that the term "fixed" and "crosslinked" are synonymous in the tissue implant art.

Claims 25 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Bayne et al (EP 0476983) wherein the fibrin coating is applied prior to the VEGF II growth factor to the

Art Unit: 3738

surface of a fixed umbilical cord vein; see the whole document, especially page 8, lines 14-26, and in particular, page 8, lines 20-23.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 9-11, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bayne et al (EP 0476983) in view of Wadstrom (5,631,011). Bayne et al discloses an implant having a fibrin coating (a biologic adhesive as claimed) which is applied prior to the VEGF II growth factor (VEGF II is the polypeptide growth factor as claimed). The fixed umbilical cord vein of Bayne et al is the substrate for coating as claimed; see page 8, lines 14-26. However, the Bayne et al cord vein, although a crosslinked human or animal tissue, is not clearly either an allograft or xenograft as claimed. Nonetheless, it is the Examiner's position that it would have been considered clearly obvious to an ordinary artisan to use an allograft or xenograft tissue for the cord vein of Bayne et al absent some showing of criticality therefor. Wadstrom is cited to show that fibrin is a common biologic tissue adhesive in the art, and thus, the fibrin coating of Bayne et al can be called and would function as a biologic adhesive as claimed.

With regard to claim 3, it is noted that the fibrin can be covalently bound to the tissue.

Art Unit: 3738

Claims 6-8, 14, 15, 21-24, and 27-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bayne et al and Wadstrom as applied to claims 1-5, 9-11, and 29 above, and further in view of Carpentier (US 5,263,992). Bayne et al fails to disclose uncrosslinked tissue, the heart valve form of the tissue, or the other tissue types as claimed. However, Carpentier teaches that all uncrosslinked and crosslinked forms of tissue, heart valve tissue forms and other types of tissue are all well known in the art; see the entire document. Hence, it is the Examiner's position that it would have been obvious to use any of these materials as the substrate of Bayne et al for the applications contemplated by Carpentier.

Claims 1-5 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cahalan et al (US 5,308,641) alone. Cahalan et al discloses a human or animal tissue solid surface wherein the glutaraldehyde crosslinking agent attaches to the growth factor biomolecule and to the spacer attached to the substrate; see the whole document, especially the abstract, column 4, lines 20-43 and column 6, lines 8-28. However, it is noted that human or animal tissue are not as narrow in scope as allogenic or xenogeneic as claimed. Nonetheless, it is the Examiner's position that it would have been considered clearly obvious to an ordinary artisan to use an allograft or xenograft tissue for the tissue of Cahalan et al absent some showing of criticality therefor.

Conclusion

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in

Art Unit: 3738

MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 of 35 USC 103(a) once the aforementioned problem is corrected.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Prebilic whose telephone number is (703) 308-2905. The examiner normally be reached on Monday-Thursday from 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for this Technology Center is (703) 305-3580.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 3700 receptionist whose telephone number is (703) 308-0858.



Paul Prebilic
Primary Examiner
Art Unit 3738